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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,071	02/03/2000	NORBERT O. REICH	30794.30USWO	1444

22462 7590 10/29/2004

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/485,071	<b>Applicant(s)</b> REICH ET AL.	
	<b>Examiner</b> Patrick T. Lewis	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31,36,37,39 and 43-48 is/are pending in the application.
- 4a) Of the above claim(s) 36,37,39,43-45,47 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of claims relating to GC box pMET, SEQ ID NO: 10 in the reply filed on August 28, 2003 is acknowledged.
2. Claims 36-37, 39, 43-45, and 47-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 28, 2003. The restriction requirement was made FINAL in the Office Action dated April 14, 2004.
3. This application contains claims 36-37, 39, 43-45, and 47-48 drawn to an invention nonelected with traverse in the Paper filed August 28, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Applicant's Response Dated August 16, 2004***

4. In the Response filed August 16, 2004, claims 31, 36-37, 39, 44-45, and 47-48 were amended, and claims 1-30, 32-35, 38, 40-42, and 49-50 were canceled.
5. Claims 31, 36-37, 39, and 43-48 are pending. An action on the merits of claims 31 and 46 is contained herein below.
6. The rejection of claims 31 and 46 under 35 U.S.C. 103(a) as being unpatentable over the combination of Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315

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(Flynn) and Billing-Medel et al. US 6,183,952 (Billing) is maintained for the reasons of record as set forth in the Office Action dated April 14, 2004.

### ***Response to Arguments***

7. Applicant's arguments filed August 16, 2004 have been fully considered but they are not persuasive. Applicant argues that Flynn does not provide a motivation for either using the substrates in a pharmaceutical composition or for introducing phosphorothioate linkages and that there is no teaching in the prior art to use GC-box b<sup>met</sup> in the context of antisense technology to prevent transcription and production of a particular polypeptide.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The examiner disagrees with applicant's characterization of the prior art. Flynn clearly teaches an oligonucleotide containing 5mCpG dinucleotide (see Table 1, page 7309). DCMTase activity has been linked to tumor development. The deoxyoligonucleotide containing CpG dinucleotide were designed to mimic DNA transcriptional cis elements previously reported to have cytosine C-5 methylated regulation. DCMTase catalyzes DNA methylation. The prior art teaches links between the instant CpG dinucleotide and tumor development and thus provides sufficient

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motivation to combine the oligonucleotide of Flynn with a pharmaceutically acceptable carrier such as water. The examiner acknowledges that Flynn does not teach phosphorothiolate linkages; however, Billing provides sufficient motivation for doing so. Applicant's attention is directed to column 26 wherein billing teaches that antisense oligonucleotides act with greater efficacy when modified to contain artificial internucleotide linkages such as phosphorothiolate linkages. Indeed, the instantly claimed oligonucleotide would have been obvious to one of ordinary skill in the art at the time of the invention. Furthermore, claiming an unpatentable compound in combination with a carrier does not render the combination patentable.

### ***Conclusion***

8. Claims 31, 36-37, 39, and 43-48 are pending. Claims 36-37, 39, 43-45, and 47-48 are drawn to a nonelected invention. Claims 31 and 46 are rejected. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

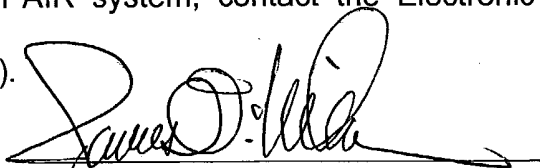
### **Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday between 10 am - 2 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Lewis, PhD  
Examiner  
Art Unit 1623



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ptl